

#### REMARKS

Claims 17 and 18 were cancelled without prejudice. Claims 1, 14 and 16 were amended to clarify the methods claimed. Support for the amendments to these claims may be found at least at page 3, line 27 - page 4, line 2. No new matter has been added. The amendments are presented to clearly put the claims in condition for allowance and meet the requirements of 37 C.F.R. § 1.116. Claims 1-16 are pending.

#### *THE REJECTIONS*

Claims 1-8 and 14-16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Witbeck et al., U.S. Patent No. 5,508,027, in further view of Bonfield et al., U.S. Patent No. 5,728,753. Claims 11-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Witbeck et al., and Bonfield et al., in further view of Zook, U.S. Patent No. 5,181,914. Claim 9 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Witbeck et al., and Bonfield et al., in further view of Shepherd et al., U.S. Patent No. 3,914,405. Claim 10 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Witbeck et al., and Bonfield et al., in further view of LeGrow, U.S. Patent No. 5,403,402. Applicants respectfully traverse each of these rejections.

#### *THE INVENTION*

Claim 1 is directed to a method for treating nails comprising applying a composition comprising an effective, nail-enhancing amount of non-interlinked particles of bioactive glass to the nails. Independent claim 14 is directed to a method for treating nails in mammals other than humans comprising applying a composition comprising an effective, nail-enhancing amount of non-interlinked particles of bioactive glass to the nails. Independent claim 16 relates to a method for treating nails comprising applying a composition comprising an effective, nail-enhancing amount of bioactive extract to the nails. Each of these methods provides that the method is conducted for a sufficient amount of time to provide that a layer of hydroxyapatite or other calcium phosphate crystals is formed on the nails and ions from

the bioactive glass or bioactive extract penetrate layers of the nails to form hydroxyapatite crystals within the layers of the nails. These methods allow enhancement of the hardness and durability of the nail body. As pointed out in the specification, calcium and phosphate ions are believed to be released from the bioactive glass or bioactive extracts which ions become available to form the calcium phosphate layer and/or to penetrate into the nail body.

*Specification, page 5, lines 23-25.* The hydroxyapatite believed to precipitate in and through the nail strengthens and hardens the nail. Thus, the crystalline phase provided gives the nail a composite structure, enhancing the nail.

#### THE ART

Witbeck relates to methods and compositions for strengthening nails by the periodic application of synthetic gums of acrylic polymer films on the nail body. The compositions may contain an alkali metal base and a volatile fragrance. The process and compositions of Witbeck involve the use of polymers and films, not the use of bioactive glass. Moreover, Witbeck does not teach methods or compositions which penetrate into the layers of the nails. Rather, the teachings of Witbeck are directed only to a *coating* which forms a continuous film on the surface of the nail body. *Column 2, lines 6-7.*

Bonfield relates to a bioactive composite material for the repair of hard and soft tissues. The compositions contain a combination of a polyolefinic binder with certain bioactive glass materials. The composites bond actively with, for example, soft tissues, and facilitate the production of implants tailored for highly specific medical requirements. Bonfield specifically teaches *interfacial* bonds, and does not teach or suggest that bioactive glass could be used to penetrate into the layers of nails. For example, Bonfield refers to the rate of formation of a biological apatite layer *on the surface* (*column 5, lines 1-2*) and presents experiments which demonstrate that all of the composites develop *surface* biological apatite layers...*column 5, lines 21-23.*

*DISCUSSION*

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. *MPEP* § 2143.

According to the Office Action, Bonfield is relied on for the teaching of particulate bioactive glass in a composition that is able to achieve attachment to soft and hard tissue by formation of a layer of hydroxyapatite from the bioactive glass material that increases the presented area and enhances formation of a biological layer. *Office Action, page 3*. The Office Action further relies on Bonfield for the teaching that the average particle size of bioactive glass ranges from about 0.5  $\mu\text{m}$  to about 500  $\mu\text{m}$ . *Office Action, page 3*. The Office Action continues:

It is the position of the examiner that it would be obvious to one of ordinary skill in this art at the time of the invention to use the teachings of Bonfield with regard to using bioactive glass as a component in a composition to repair soft and hard tissue in the teaching of Witbeck because Bonfield teaches that damaged nails can be strengthened and repaired by adding a composition for an extended period of time as in Witbeck.

*Office Action, page 3 (emphasis added).*

The first requirement of a *prima facie* case of obviousness is a suggestion in the art to modify or combine the cited art. The Office Action seems to indicate that such motivation comes from Bonfield's teaching regarding hard and soft tissues which are allegedly recognized by the art to include nails. *Office Action, page 6*. However, Bonfield does not

include any teachings specific to nails nor does it mention the material from which nails are made, keratin. Moreover, Bonfield does not include any description of damaged nails. Although Bonfield does mention hard and soft tissues, there is no teaching as detailed by the Office Action which would have led one of skill in the art to the present invention or to any combination with a patent directed to nail coatings like Witbeck.

Moreover, Bonfield does not teach that applying bioactive glass to nails (or any hard or soft tissue), would result in the ions of the bioactive glass or glass extract penetrating into the pores of those nails (or any tissues) as found by the present inventors. Rather, Bonfield teaches the precipitation of a layer of bioactive glass which bonds to tissues, providing a bioactively derived tissue bonding across the interface of, for example, a prostheses and the tissue. *Column 6, lines 18-19*. The present invention provides for a chemical bond within the nail tissues which causes changes in the properties of the nails themselves as ions from the bioactive glass or glass extract penetrate layers of the nails to form hydroxyapatite crystals within the layers of the nails. These changes result in enhancement of the hardness and durability of the nail body.

Bonfield, on the other hand, teaches a connection between the tissue of the body and the composite material or implant taught by Bonfield. This connection is an interfacial bond, not a penetration into the tissue by ions as claimed herein. Bonfield does not teach a change in the tissue itself. Moreover, Bonfield does not describe a method which results in hardness of the tissue bonding with the composite material. Bonfield does not and could not provide motivation to one of ordinary skill in the art to perform the claimed methods since Bonfield does not recognize the ability of the bioactive glass to penetrate layers of tissue, specifically, the nails, as claimed, to provide an enhancement of nails as achieved by the claimed methods.

Nothing in Witbeck provides the necessary motivation to combine the teachings of Bonfield and Witbeck, either. Witbeck does not teach or suggest anything other than a film on the surface of the nail. Such a film does not provide the advantages of the claimed methods. Neither Bonfield nor Witbeck disclose the nail enhancing ability of bioactive glass

discovered by the present inventors. In view thereof, one of skill in the art would not have been motivated from the cited art to perform the methods as claimed. Additionally, there would not have been any motivation to combine the teachings of Bonfield and Witbeck as neither patent relates to a method for treating nails which provides as claimed.

The second requirement for a *prima facie* case is a reasonable expectation of success. Such could not be gleaned from either Bonfield or Witbeck in view of their total lack of recognition of the advantages obtained by the claimed methods upon application of bioactive glass as claimed.

The final requirement for a *prima facie* case of obviousness is that the cited art must teach or suggest all the claim limitations. This is clearly not the case here. Nothing in either Bonfield or Witbeck describes or suggests the claimed methods directed to treating nails such that both a layer of hydroxyapatite or other calcium phosphate crystals is formed on the nails, and ions from the bioactive glass penetrate layers of the nails to form hydroxyapatite crystals within the layers of the nails.

In view of the lack of each requirement necessary for a *prima facie* case of obviousness, Applicants respectfully request that each of the rejections under 35 U.S.C. § 103 be withdrawn. Since there is no motivation to combine the cited art, no reasonable expectation of success, and no teaching or suggestion of all the claim recitations, the combination of Witbeck and Bonfield would not have made the claimed invention obvious. The additional art cited against the claims also fails to provide a *prima facie* case of obviousness. Therefore, Applicants respectfully request that each of the rejections be withdrawn. In light of the above amendments, Applicants believe the claims are now in condition for allowance.

#### COMPARATIVE DATA PROVIDING EVIDENCE OF NONOBVIOUSNESS

As discussed above, neither Witbeck nor Bonfield teach or suggest that bioactive

glass can provide a layer of hydroxyapatite or other calcium phosphate crystals on the nails and that ions from the bioactive glass penetrate layers of the nails to form hydroxyapatite crystals within the layers of the nails. Thus, a *prima facie* case of obviousness has not been presented and Applicants are not required to present information traversing the rejections of the Office Action. However, in order to expedite prosecution of the application and in response to a specific request (See Examiner Interview Summary Record, May 1, 2001), particular evidence was presented illustrating the characteristics of the bioactive glass disclosed and claimed in the present application. This evidence shows the results obtained by the present inventors with the claimed method for treating nails. This result is not taught or suggested by the cited art. Evidence traversing rejections must be considered by the examiner whenever present. *MPEP* § 716.01.

At the interview May 1, 2001, Applicants were requested to provide comparative data showing that other calcium ion generating solutions do not have the effect of bioactive glass on nails. A Declaration under 37 C.F.R. § 1.132 was presented with Applicants' Amendment Accompanying RCE filed July 5, 2001. As shown in the declaration, hydroxyapatite only precipitated onto the surface of the nail upon exposure to bioactive glass (Legs #1 and 2). The portions of the experiment using calcium solution, a bioinert glass or a buffer did not result in the precipitation of hydroxyapatite on the nails.

Thus, Applicants have submitted evidence of nonobviousness in the form of results not taught by the cited art. The cited art does not teach that use of bioactive glass as claimed would provide a layer of hydroxyapatite or other calcium phosphate crystals on the nails or that ions from the bioactive glass penetrate layers of nails as found by the present inventors. Neither Bonfield nor Witbeck disclose the nail enhancing ability of bioactive glass discovered by the present inventors. Thus, the claims are believed to be allowable over the cited art.

Applicants believe they have responded to all matters raised in the above referenced Office Action and that the application is now in condition for allowance. If the Examiner

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has any questions concerning this Application or this Reply and Amendment, she is invited to contact the undersigned.

Respectfully submitted,

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